REMARKS/ARGUMENTS

Status of the Application

In the Advisory Action, claims 31-32 were allowed, claims 33-34 and 47-48 were rejected, and claims 49-51 were not entered because "the claims raise new issues that would require further search and consideration." In the present response, claims 49-51 are re-presented (see page 24, lines 1-9, for support). Claims 47 and 48 were canceled without prejudice. Applicant reserves the right to pursue these claims in any application derived from the present application. Thus, claims 31-34 and 49-51 are pending. No new matter was added.

Applicant acknowledges and thanks the Examiner for the allowance of claims 31-32.

Rejections Under 35 U.S.C. § 112, 1st Paragraph

Claims 33 and 34 were rejected under 35 U.S.C. § 112, 1st Paragraph, as failing to comply with the written description requirement. In the Final Office Action, the Examiner termed this rejection "A New Matter Rejection." Applicant respectfully traverses this rejection.

In the specification as filed, fragments of SEQ ID NO:32 (and all other amino acid sequences) are defined as "amino acid sequences coded by the above nucleic acid fragment, *containing regions by which the variant differs from the original sequence* as indicated in Table 1." (page 22, lines 25-27; emphasis added). The "above nucleic acid fragment" is "a partial sequence of any one of SEQ ID NO:1 to SEQ ID NO:21 which includes the regions which contains [sic] the variation in nucleotides between the variant and the original sequences. The regions (in the amino acid level) are as depicted in . . . Table 1." (page 22, lines 19-23). Thus, the definition of "fragments" for both the amino acid sequences and the nucleic acid sequences disclosed in the present application clearly indicates that a region which differs from a wild type sequence must be included in the fragment.

Claims 33 and 34 reflect this requirement. In Table 1, the description of SEQ ID NO:32 notes that ghrelin variant 2 (SEQ ID NO:32) differs from wild-type ghrelin in that "[a]lternative 70 amino acids from position 35 in the wild type

protein creating a variant with 117 amino acids." (Table 1, page 7).[1] A comparison of the wild type sequence (SEQ ID NO:31) with the claimed ghrelin splice variant confirms the differences between the sequences is consummate with the scope of claims 33 and 34 (see Figure 3). Amino acids 1-35 of both SEQ ID NO:31 and SEQ ID NO:32 are identical. After alternative splicing, the splice variant coincidentally has the same amino acid at position 36 as the wild type protein, but subsequent to amino acid 36, the sequences are substantially different. Consequently, Applicant has claimed fragments that contain a region having at least one difference between wild type ghrelin and the SEQ ID NO:32 splice variant, namely fragments which contain at least one contiguous amino acid from amino acids 37-117 of SEQ ID NO:32.

While Applicant understands that written description analyses are factually dependent and are thus decided on a case-by-case basis, *In re Johnson*, 558 F.2d 1008 (CCPA 1977), is sufficiently similar to the present situation to warrant discussion. In *Johnson*, the applicants' originally filed application disclosed two precursor compounds for the formation of linear thermoplastic polyarylene polyether polymers. *Johnson*, 558 F.2d at 1009-10. Applicants' specification disclosed 50 compound choices for one of the precursors and a broad class of suitable choices for the other precursor. *Id.* at 1018. After losing an interference on the broad claims, the applicants amended the claims to exclude the possibility of the two precursor compounds both having a divalent sulfone group and both having a divalent carbonyl group, the subject matter of the lost interference count. *Id.* at 1013. The Examiner and the Board of Patent Appeals agreed that there was no support for this narrowing amendment in the specification, calling applicants' amendment the creation of a new subgenus. *Id.* at 1014. The court disagreed noting that

> [t]he notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species there within, has somehow failed to disclose, and teach those skilled in the art how to make and use, that genus minus two of those species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the

[1] Note that the number "70" in the ghrelin splice variant 2 section of Table 1 is an obvious error; there are 82 amino acids after position 35 in SEQ ID NO:32.

> statute. All that happened here is that appellants narrowed their claims to avoid having them read on a lost interference count.

Id. at 1019. In holding that the specification adequately described the narrower invention, the court further noted that the applicants in *Johnson* were "merely excising the invention of another, to which they [were] not entitled, and [were] not creating an 'artificial subgenus' or claiming 'new matter.'" *Id.* As the ghrelin splice variant disclosed and claimed by the Applicant has the same amino acid at position 36 as the wild type, Applicant here has claimed fragments of SEQ ID NO:32 beyond position 36, that is, the region of SEQ ID NO:32 which differs from SEQ ID NO:31, as set forth in definition provided in the specification as filed. Similar to *Johnson*, Applicant has not created an artificial subgenus, but is merely claiming less than what was originally claimed.

Claim language does not have to appear *ipsis verbis* in the specification to satisfy the written description requirement. MPEP § 2163.02. Here, it would probably violate section 112, 2nd paragraph, to claim fragments as those "containing regions by which the variant differs from the original sequence as indicated in Table 1." By specifically defining the fragments as containing at least a part of amino acids 37-117, the same concept as presented in definition of "fragments" is covered in the claims in a manner which complies with section 112, 2nd paragraph.

Consequently, Applicant respectfully submits that the amendment narrowing the scope of the fragment claims to those containing a portion of the variant sequence does not constitute new matter and is fully supported by the specification as filed.

Claims 33-34 and 47-48 were rejected under 35 U.S.C. § 112, 1st Paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses these rejections.

Applicant incorporates the arguments above for the "new matter rejection" in response to this written description rejection for claims 33 and 34. Further, Applicant respectfully disagrees with the Examiner's assertion that claims 33 and 34 are not supported by adequate structure in the specification. "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from

other materials." *Regents of the Univ. of Calif. v. Eli Lilly & Co.*, 119 F.3d 1159, 1568 (Fed. Cir. 1997) (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)) (modification in original). Here, the structure of the claimed genus is disclosed in the specification. Because SEQ ID NO:32 defines exactly the differences between wild type ghrelin and the claimed splice variant, every claimed fragment of the splice variant can be readily envisioned from the disclosure. As a result, *every* species of the genus is disclosed. In turn, Applicant should be able to claim the genus. MPEP § 2163(II)(A)(3)(a)(ii).

The Examiner has ignored the fact that *all* of structure claimed in claims 33 and 34 has been identified in the present disclosure. Disclosure of every species here is similar to situations in the chemical art where a general formula discloses every species through potential substituents. In those cases, an applicant is entitled to the genus because "[o]ne skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." *Eli Lilly*, 119 F.3d at 1568. The present disclosure should similarly entitle the Applicant to a genus encompassing the disclosed fragments.

Further, the present disclosure does not merely make the claimed fragments obvious; the fragments are inherently disclosed by SEQ ID NO:32 in combination with the definition of fragments. *See Id.* at 1567 ("a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention") (citing *Lockwood v. Amer. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). An express disclosure would simply encompass a complete list of all of the claimed fragments. An express disclosure, however, is not necessary for written description purposes, as an inherent disclosure satisfies section 112, 1st paragraph. MPEP § 2163(I)(B) ("While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure."). While Applicant does not believe it to be necessary in the present case, a complete list of all fragments can be supplied at the Examiner's request.

Because claims 47 and 48 were canceled, the rejections thereof are moot.

Summary

In view of the foregoing amendments and remarks, Applicant submits that this application is in condition for allowance. In order to expedite disposition of this case, the Examiner is invited to contact Applicant's representative at the telephone number below to resolve any remaining issues. Should there be a fee due which is not accounted for, please charge such fee to Deposit Account No. 501447 (Potter Anderson & Corroon LLP).

Respectfully Submitted,

By: _____

Jeffrey B. Saffan
Attorney for Applicants
Reg. No.: 54,689
Telephone: (302) 984-6132
Facsimile: (302) 658-1192

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